

REMARKS

Reconsideration of the present application as amended is requested. It was noted that the original application included two claims numbered 38. The second of the duplicate claims (38(B)) has been cancelled in response to a prior restriction requirement, so no issue remains with respect to the duplicate claim numbering.

Deficiencies in two entries in Applicants' prior submitted IDS were noted. Applicants have submitted a new IDS to address these deficiencies and to identify a newly discovered reference.

The objection to claim 36 has been obviated by an amendment to that claim. In response to the rejection of claim 37 as indefinite, Applicants have further amended claims 36, 37, 46 and 47 to more precisely identify the components of the motions segments to which the bone anchors are engaged. As used in the present application, a spinal motion segment includes a spinal disc and the two vertebrae flanking that disc, which is consistent with the ordinary usage of the term "motion segment" in the art. The present claims have been amended to more clearly comport with this standard usage.

The obviousness rejection of claim 36

Claims 36-38 and 41-47 were rejected as obvious over the primary combination of published applications to Dixon et al. and Muckter. With respect to independent claim 36, the Dixon reference was said to disclose every feature except the limitation that at least one bone anchor is coupled to permit deflection of the bone anchor between the stabilization element and the motion segment. It is first noted that this limitation has been amended to refer to the vertebra to which the bone anchor is engaged, rather than to the motion segment in its entirety.

The Dixon reference discloses a stabilization element in the form of a slotted plate 42 that spans a length of the spine and that is positioned adjacent the spine. Dixon also discloses bone anchors in the form of bone screws 47 that are engaged within vertebrae. Each bone screw is coupled to the slotted plate by way of bone screw clamp portions 26, 45 and a machine screw nut 46. See, Dixon, FIGS. 2-3. The Office Action correctly notes that this coupling between the bone screw and plate in Dixon does not

permit deflection of the bone screw (bone anchor) between the slotted plate (stabilization element) and the associated vertebra.

The Muckter published application was cited for its disclosure of a bone screw having a flexible shaft 3 between the head 1 of the screw and the threaded part 2 of the screw. This flexible shaft is described as preventing relative movement in the direction of tension – i.e., axially along the length of the screw – while permitting small movements in all other directions. See, Muckter Abstract. The screw in Muckter "makes it possible for both bones involved in a joint injury or both fragments involved in a bone injury to be joined" in a manner that "guarantees transfer of tensile forces almost exclusively, while bending moments, compressive forces and transverse forces are not transmitted at all." See, Para. 0015. Thus, Muckter only contemplates connecting two bone segments with the disclosed screw, and does not contemplate engaging the bone screw to a separate device, such as a stabilization element in the form of a plate or a rod.

The obviousness rejection of claim 36 is predicated on replacing the bone screws of Dixon with the bone screws of Muckter. The rationale set forth in the Office Action in support of this substitution is that doing so would eliminate the need to use a spacer to achieve dynamic stabilization. This purported rationale entirely ignores the primary purpose of the apparatus in Dixon. Eliminating the spacer in the Dixon apparatus completely destroys the function of the invention disclosed in that published application. As best expressed in claim 1 of the Dixon application, the disclosed screw-plate system will "selectively allow one or more vertebrae to move freely toward or to be forced into compression with an adjacent vertebra or implant." This language carries through the remaining claims of the Dixon application. In the specification, Dixon explains that the disclosed invention will provide stress shielding in six directions of motion of the vertebrae. See, Dixon, Paras. 0053-0059.

However, Dixon highlights that the disclosed invention "will allow for axial subsidence or compression at the fusion interface", and that "[t]his compression is desirable because it tends to prevent lateral motion at the fusion interface and promotes improved vascularization of the graft." Dixon, Para. 0060. The "dynamized action" referred to in Dixon is not deflection of the bone screw between the plate and the vertebra, as required by Applicants' claim 36. The "dynamized action" in Dixon is the

axial motion of the bone screw relative to the length of the plate. See, Dixon, Para. 0049. This axial motion is critical to the Dixon apparatus because it allows the use of the "rigidizing stop locks" to control or limit that axial motion for "unidirectional dynamized (subsidence) action of the bone screw assembly 49 with respect to the plate 42." Dixon, Para. 0051. Eliminating the spacers in Dixon would render the stop locks useless. Moreover, eliminating the spacers would destroy the versatility of the Dixon apparatus described in Paras. 0064-0067.

Adding additional degrees of freedom of movement to the bone screws in Dixon would also destroy this versatility. In other words, if the bone screw in Dixon were modified to permit bending between the plate and the vertebra, it would be virtually impossible to apply a compression preload, as described in Para. 0067 of Dixon. The use of springs in the stop locks to maintain compression on the vertebra/graft interface, described in Para. 0051, would also be virtually impossible since the spring force would be absorbed by deflection of the bone screw rather than transmitted to the vertebra. Moreover, any axial subsidence of the vertebra would be absorbed by deflection of the modified bone screw, rather than transmitted to the plate and stop lock.

The purported rationale for substituting bone screws set forth in the Office Action completely discards the "dynamized action" that is the entire foundation of the invention in the Dixon application. The Office Action rationale requires substituting an entirely different "dynamic stabilization" than would be understood from the Dixon reference. In essence, the sole support for the obviousness rejection is that a person of ordinary skill would look at the Dixon reference and decide that a different type of "dynamized action" would be preferable to the "dynamized action" disclosed in Dixon. Broken down even further, the alleged basis for finding obviousness is simply the recognition that a stabilizing system can provide stress shielding in the six degrees of vertebral motion described in Paras. 0054-0059. Dixon's answer is to prevent movement of the bone screw between the plate and the vertebra, but permit sliding of the entire bone screw along the length of a slotted plate. Applicants' novel apparatus works exactly the opposite – the movement of the bone screw between the stabilization member and the vertebra is permitted so axial sliding is not required.

The obviousness rejection of claim 36 is not supported by the "rational underpinning" required under the PTO examination guidelines following the *KSR* decision. None of the various rationales set forth in the PTO guidelines apply in this case. The combination of the Dixon and Muckter applications does not entail the combination of prior art elements according to known methods to yield a predictable result. First, the cited combination requires eliminating components from the Dixon apparatus, as explained in the Office Action. Second, no explanation has been provided as to how the bone screw construction of the Muckter device can be engaged to the slotted plate of Dixon. Finally, no predictable result has been identified for engaging the flexible bone screw of Muckter with the slotted plate of Dixon. For instance, given the structure of the Muckter screw it would appear that positioning a screw within the slotted plate of Dixon and then threading that screw into a vertebra would necessarily draw the plate into contact with the vertebra.¹ When the plate is in contact with the vertebra, any flexibility in the bone screw is irrelevant because there is no exposed portion of the bone screw that can move. If the Muckter-type screw is not fully threaded into the bone, then the Dixon slotted plate is free to slide up and down along the length of the screw. It is inconceivable that a person of ordinary skill would consider such a construct to achieve stabilization of a spinal motion segment during fusion.

The second rationale offered in the PTO guidelines – simple substitution of one known element for another to obtain predictable results – fails for the same reasons. No explanation was offered in the Office Action as to how the Muckter flexible screw can be implemented with the Dixon slotted plate, nor does a rationale explanation exist. In fact, all of the proposed rationales in the PTO guidelines fail for these same reasons. All of the suggested rationales require some reasonable expectation of success. Moreover, the current standards of patentability have not ejected the traditional rule that a proposed combination is not obvious where it will frustrate or destroy the functionality of a component of the combination. As explained above, eliminating the spacer from the Dixon device would destroy its utility, versatility and functionality.

¹ For instance, the Martin patent cited in the Office Action shows a plate 7 anchored in contact with the vertebra by a bone screw 17 similar in construction to the Muckter screw. See, FIG. 2.

For all of the foregoing reasons, it is believed that no prima facie case for obviousness of claim 36 has been presented in the Office Action. The analysis and suggested motivation expressed in the Office Action fail to satisfy any of the current PTO guidelines for establishing obviousness. Since Applicant has traversed the rejection of claim 36, it is believed that this claim and its dependent claims 37-38 are patentable over the art of record.

The obviousness rejection of claim 41

The Dixon and Muckter references were also applied in the obviousness rejection of independent claim 41. Claim 41 includes the step of coupling a dynamic stabilization system across a motion segment in which the system includes a bone anchor that can be deformed. Again, the combination of Dixon and Muckter was said to meet this element of claim 41. For the reasons set forth above, this combination fails to meet this limitation of claim 41. This failure of Dixon and Muckter is sufficient to overcome the obviousness rejection of claim 41.

It was further suggested that the Serhan, Bao and Martin patents establish the obviousness of Applicants' claim 41 combining the step of introducing a device to restore the natural disc motion with the step of coupling a dynamic stabilization system across the motion segment. Dixon contemplates a method for stabilizing lumbar vertebrae during fusion. See, Dixon Abstract, Para. 0040. The cited Bao patent discloses one type of disc nucleus replacement, but does not disclose providing any form of stabilization to the implanted device. The Serhan patent discloses a prosthetic ligament as a temporary stabilization system for spine fusion (Serhan, Para. 0062) or until a "motion disc" has time to osteointegrate with the vertebral endplates (Serhan , Para. 0076).²

The Serhan reference is particularly instructive as to the non-obviousness of the method steps of Applicants' claim 41. Specifically, Serhan discloses the use of a "connection system" that prevents the natural motion of the disc either after the "motion

² In view of the disclosure of both fusion and "motion disc" in Serhan it is believed that the citation of the Martin patent to demonstrate the need to replace a disc is unnecessary. Moreover, the Martin patent concerns a facet joint prosthesis that is essentially independent of the disc itself. Thus, the cited excerpt in Martin provides no support the alleged obviousness of combining dynamic stabilization with a disc replacement device, as suggested in the Office Action.

disc" has integrated with the adjacent vertebrae, at which time the connection system disappears. In particular, Serhan explains that "the resorption time of the [bioresorbable] ligament can be tailored such that the ligament resorbs slightly after the osteointegration of the motion disc endplates occurs. When the ligament portion bioabsorbs, the motion disc is free to flex. In this case, the resorption feature eliminates any concern that the ligament will restrain motion afforded by the motion disc." Serhan, Para. 0076 (emphasis added). Serhan contemplates that the ligament and bone fastener is pre-formed so that "there is no danger of micromotion." Serhan, Para. 0163. Thus, Serhan only contemplates a stabilization system that limits motion of the disc. See, also, Serhan, Para. 0114.

In other words, Serhan does not disclose the combination of a disc replacement and a dynamic stabilization system, as recited in claim 41. On the other hand, while Dixon discloses one form of dynamic stabilization (dynamized action) it only discloses such stabilization in conjunction with fusion. If Serhan can be combined with Dixon at all, the end result is a system that prevents the natural motion of the disc while spinal fusion occurs. Substituting the hydrogel disc prosthesis of Bao for the disc replacement of Serhan does nothing to overcome this conclusion. This incompatibility between the disclosures of Dixon and Serhan cannot be brushed aside. The Office Action contains no explanation as to how this incompatibility can be resolved. The PTO guidelines for establishing obviousness have not eliminated the need to provide a rational basis for the proposed combination beyond simply selecting components from the prior art to be combined without regard to whether the combination is viable to a person of ordinary skill in the art.

Applicants have traversed the proposed combination of references as well as the obviousness rejection of independent claim 41. It is therefore believed that this claim and its dependent claims 42-47 are allowable over the art of record.

The obviousness rejection of claim 48

Independent Claim 48 is similar to independent claim 41, except that the step of coupling a dynamic stabilization system does not require a deformable bone anchor. However, like claim 41, claim 48 requires that the stabilization system permit natural

motion of the disc of the instrumented motion segment. Independent claim 48 was rejected as obvious in view of the combination of Dixon, Serhan, Bao and Martin. The failings of this proposed combination are fully explained above. The incompatibility of the Dixon and Serhan disclosures would not be sufficient to lead a person of ordinary skill to make the combination suggested in the Office Action. This, it is believed that independent claim 48 and its dependent claims 49-51 are patentable over the cited art.

Conclusion

The obviousness rejections of the pending claims are not supported by the rational underpinning required under the PTO guidelines applying the *KSR* decision. The rejections amount to nothing more than a selection of features from the prior art that meet certain limitations of Applicants' claims, without regard to whether or how these features might be combined by a person of ordinary skill in the art. The suggested rationale of eliminating the spacer of the Dixon apparatus nullifies the entire Dixon invention and completely destroys the versatility and functionality of the apparatus disclosed in that patent.

It is requested that the rejections of pending claims 36-38 and 41-51 be withdrawn and that action be taken toward a Notice of Allowance.

Respectfully Submitted,

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